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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,469	12/03/2004	Akira Nishiyama	Q83579	6750
<div>23373 7590 07/27/2007</div> <div>SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037</div>				
			<div>EXAMINER</div> <div>KUMAR, SHAILENDRA</div>	
			<div>ART UNIT</div> <div>1621</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>07/27/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/516,469	Applicant(s) NISHIYAMA ET AL.	
	Examiner SHAIENDRA -. KUMAR	Art Unit 1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 and 71 is/are pending in the application.
4a) Of the above claim(s) 22-46 and 55-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21, 47-54 and 71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This office action is in response to applicants' communication filed on 5/4/07.

Claims 1-60 and 71 are pending in this application. Claims 22-46 and 55-60, stand withdrawn from the consideration, being drawn to the non elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-21 and 71 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al in view of Matsuo et al, all for the reasons of record.

Instant claims are directed to a process of preparing optically active alpha substituted aminoketone, by reacting alpha substituted ketone with an optically active amine and isolating diastereomer from the mixture with an acid, for example methanesulfonic acid. Claims are also drawn to the optically active amino ketone compounds per se.

Muller et al is teaching a process of preparing stereoisomers of the amino ketone compound, see page 451, lines 11-21. The difference between the reference and herein claimed process is that the reference does not mention methanesulfonic acid for preparation of stereoisomers.

Matsuo et al is teaching a process of preparing optically active amino ketone, wherein it is expressly taught that use of methanesulfonic acid is old in the preparation of optically active amino ketone, see for example, column 8 and various examples.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Muller et al by using the methane sulfonic acid as taught by Matsuo et al, because the latter reference is expressly teaching that use of methane sulfonic acid is old in the art of making stereo isomers of amino ketone.

Applicants' arguments were fully considered and were not found convincing. Applicants argue that Muller et al disclose racemic amine as against optically amine in herein. The examiner will like to point out that inasmuch as the process involves production of enantiomers using methanesulfonic acids, use of racemic and optically active amine would produce same results, absent evidence to the contrary. In re Adamson, 275 F. 2d 952, 125 USPQ 233. Likewise, applicants' arguments regarding

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compound 1b on pages 450 and 452, can be argued with respect to the above case law. Muller et al may not be teaching methane sulfonic acid, however, Matsuo et al is expressly teaching the same. Applicants' arguments that methanesulfonic acid has different purpose in the reference is of little if any probative value inasmuch as methane sulfonic acid is very well known agent for obtaining optically agent.

5. Claims 47-54 are again rejected under 35 U.S.C. 103(a) as being unpatentable over Muller et al, optionally in view of Matsuo et al.

Muller et al is teaching structurally similar compounds as claimed herein, see for example page 451, lines 11-21. the difference between the reference and herein claimed compounds is that the reference does not disclose optical isomerism of the compounds.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain stereoisomers of the compounds, because stereoisomers of the compounds are obvious. *Sterling Drug v. Watson*, 108 USPQ 65. Notwithstanding that, Matsuo et al is expressly teaching a process of obtaining optically active compound, and Muller et al itself uses the stereoselection, see page 451, line 6. and herein claimed process is that the reference does not mention methanesulfonic acid for preparation of stereoisomers.

Matsuo et al is teaching a process of preparing optically active amino ketone, wherein it is expressly taught that use of methanesulfonic acid is old in the preparation of optically active amino ketone, see for example, column 8 and various examples.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Muller et al by using the methane sulfonic acid as taught by Matsuo et al, because the latter reference is expressly teaching that use of methane sulfonic acid is old in the art of making stereo isomers of amino ketone.

Applicants argue that the purpose of Matsuo methanesulfonic acid is different than claimed herein. It is well known that methane sulfonic acid is well known agent for obtaining stereoisomers. Also see *Sterling Drug v. Watson*, 108 USPQ 65.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

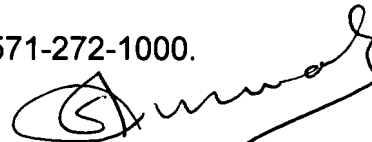
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to **SHAIENDRA - KUMAR** whose telephone number is (571)272-0640. The examiner can normally be reached on Mon-Thur 8:00-5:30, Alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (571)272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



SHAIENDRA - KUMAR
Primary Examiner
Art Unit 1621

S.Kumar
7/23/07